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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1789 1:06-md-1789 (JFK)
This Document Relates to:		
ALL ACTIONS	)	**ORAL ARGUMENT REQUESTED**

DEFENDANT MERCK SHARP & DOHME CORP.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR ENTRY OF A *LONE PINE* ORDER

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Defendant Merck Sharp & Dohme Corp. ("Merck") respectfully submits this memorandum in support of its motion for entry of a Case Management Order ("CMO") in the form appended to its motion.

PRELIMINARY STATEMENT

Since MDL-1789 began in the fall of 2006, the Court has diligently furthered the purpose of 28 U.S.C. §1407 to "promote the just and efficient conduct of [the] actions" that comprise the MDL. The litigation is now at a stage where it is appropriate to enter a CMO that will further promote the just and efficient conduct of these proceedings by ensuring that a process is put in place to eliminate meritless cases from the MDL. Merck thus seeks a CMO that will compel each Plaintiff to confirm, by appropriate means, that she has sufficient basis to claim that Fosamax caused the injury she has alleged. The CMO Merck seeks would put into place a Lone Pine process of the kind "widely used in mass torts," like this, "to isolate spurious claims." David F. Herr, ANN. MANUAL FOR COMPLEX LIT. § 11.34 (4th ed. 2012).

For six years now, individual Plaintiffs and their counsel have had the benefit of extensive factual and scientific discovery from Merck and ample time to evaluate their cases in light of that discovery. As a result of the hard work of this Court as well as the attorneys and their clients that have been before it, individual Plaintiffs in MDL-1789 have been afforded benefits unavailable to the typical tort plaintiff. For example, each individual Plaintiff has had the ability to observe in real time and review after the fact how specific causation issues have been presented through retained experts and treating physicians during the course of the bellwether trials. In part because of this knowledge, the mere prospect of trial has compelled a dismissal rate of greater than 50% for those cases that have been selected for trial.

Compelling Plaintiffs to demonstrate that they can cross the basic threshold of proffering causation evidence imposes no duty on Plaintiffs greater or different than what they already face, and has the very real prospect of efficiently narrowing the number of cases for resolution and potential remand. Plaintiffs and their attorneys -- who when pressed to support their claims against Merck that Fosamax caused them injury have repeatedly and at a high rate been unwilling or unable to do so -- can proffer no valid reason why the entry of such a CMO would not further the interests of this MDL. Lone Pine now will benefit:

1) The resolution process, by identifying and eliminating from the global settlement discussions the meritless claims that impede informed dialogue;

2) This Court and potential transferee courts, by culling spurious claims from current and potential future dockets;

3) Merck, by eliminating lawsuits that should never have been brought against it; and

4) Plaintiffs who can satisfy the Lone Pine requirements, whose claims would move closer to determination when freed from the claims of Plaintiffs who have no basis to claim that Fosamax has caused them injury.

Accordingly, Merck urges the Court to enter an Order in the form of the proposed CMO attached to Merck's motion as Exhibit 1. Such an order will likely reduce the number of cases on the Court's docket, facilitate the possibility of global resolution by ensuring that meritless cases are not part of any resolution formula, and reduce the number of cases that may ultimately be eligible for remand. Moreover, requiring Plaintiffs to produce reports from qualified experts may assist the parties in further identifying issues that are appropriate for ruling by the Court prior to remand and will assist in further procedures Merck would propose after such an Order, which would

include the work-up and completion of fact discovery for a substantial number of randomly selected cases.

FACTUAL BACKGROUND

MDL-1789 -- August 2006 To October 2012

The J.P.M.L. established MDL-1789 in August 2006; since that time, the MDL has grown to over 1,000 cases. During the six years of this MDL, Merck has produced over 11 million pages of documents, had 24 of its company witnesses deposed, responded to numerous other discovery requests, including interrogatories and requests for admission, and, of course, defended itself in five trials of four bellwether cases.

Since its creation, MDL-1789 has proceeded in an orderly "staged" fashion, moving from the very early days where a framework for the proceedings was established (late 2006-early 2007), through discovery focused at first almost exclusively on Merck as the defendant and later on a select number of bellwether-eligible cases to be set for early trial (2007-2008), through expert reports, discovery, and briefing in advance of the earliest trials (late 2008-early 2009), and, over the last three-plus years since the first Boles trial began in August 2009, into the bellwether process where multiple cases have been tried to verdict, with another case (Scheinberg) set to begin in January 2013.[1] While the recent focus in the MDL has been on the bellwether trials, numerous other activities have taken place throughout this time, including Merck's continued receipt, review, and

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1. The cases tried to verdict thus far in MDL-1789 are:

   Boles -- 9/09 (hung jury), 7/10 (Plaintiff's verdict)

   Maley -- 5/10 (Defense verdict)

   Graves -- 11/10 (Defense verdict)

   Secrest -- 10/11 (Defense verdict).

follow-up on Plaintiff Profile Forms ("PPFs") submitted in the individual cases, and both sides' participation in mediation proceedings before former Fordham Law School Dean John Feerick that began at the end of last year.

History Of Case Dismissals In MDL-1789

While only a small percentage of the cases currently pending in this MDL have been the subject of individual attention by this Court, over one hundred cases that were at one time on this Court's docket have nevertheless been dismissed. As seen in the chart below, the likelihood of Plaintiffs dismissing non-meritorious cases increases in direct proportion to the attention paid to them:

MDL-1789 Cases	Total	Dismissed	Dismissal Rate
Total (Past And Present)	1,094	138	13%
Cases Selected For Discovery	35	11	31%
Cases Set For Trial	12	7	58%

What this chart says about the claims that have been brought in this MDL, and the support for each of the entries in it, is discussed in greater detail at pp. 10 - 15, *infra.*

Prior Consideration Of Entry Of A Lone Pine Order In MDL-1789.

Merck first raised the possibility of a Lone Pine Order by letter to the Court dated January 27, 2010. Merck's original request was made in advance of an MDL conference that had been convened to address what should be done about the fact that the Court's random selection for the second MDL bellwether trial -- Flemings v. Merck & Co., Inc., 1:06-cv-7631 -- had been dismissed just weeks before trial began based on the Court's finding that "the lack of admissible evidence on the issue of specific causation entitles

Merck to dismissal of all of Plaintiff's claims." Flemings Summ. J. Op. & Order at 22, Nov. 23, 2009. At the February 1, 2010 conference, the Court stated as follows:

> I don't think we're at the stage here where I'm going to get into lone pine now. I may well later, and so I'm advising everybody that I may later, and after we try the three bellwether cases, assuming that we get verdicts in them this time, we'll revisit it and you can make a formal application to me, [Merck], in the form of a motion.

(Conf. Tr. 11:13-18, Feb. 1, 2010.)

On September 20, 2012, Merck wrote again pursuant to this Court's pre-motion requirements to raise the issue of entry of an appropriate Lone Pine Order. After exchange of correspondence, the Court directed Merck to file its formal motion requesting entry of such an Order by this Court, which Merck now does by this memorandum and the motion that accompanies it.

ARGUMENT

I. THE COURT HAS AUTHORITY TO ISSUE A LONE PINE ORDER.

The Federal Rules of Civil Procedure vest this Court with the necessary authority to enter an order requiring Plaintiffs to demonstrate a basis for their claims. Under Federal Rule of Civil Procedure 16, district courts "are afforded wide discretion" to issue case management orders to "handle the complex issues and potential burdens on defendants and the court in mass tort litigation."[2] Acuna v. Brown & Root Inc., 200 F.3d 335, 340 (5th Cir. 2000); See also Jorgensen v. Cassiday, 320 F.3d 906, 913 (9th Cir.

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2. Rule 16(c)(2)(L) specifically contemplates that district courts may take appropriate action to address the need to "adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems." Fed. R. Civ. P. 16(c)(2)(L). No particular techniques for controlling complex cases are identified by Rule 16, because the Committee "felt that flexibility and experience are the keys to efficient management of complex cases. Extensive guidance is offered in such documents as the *Manual for Complex Litigation*." Advisory Committee Notes, 1983 Amendment to Fed. R. Civ. P. 16, subdivision (c).

2003); Landry v. Air Line Pilots Ass'n Int'l AFL-CIO, 901 F.2d 404, 436 n. 114 (5th Cir. 1990).

II. COURTS COMMONLY ISSUE LONE PINE ORDERS IN MASS TORT PROCEEDINGS TO WEED OUT SPURIOUS OR UNSUSTAINABLE CLAIMS.

A court order that requires each plaintiff in a mass tort case to submit a report setting forth evidence sufficient to document the basis for his or her personal injury claims is frequently called a Lone Pine Order based upon the holding in Lore v. Lone Pine Corp., No. L-33606-85, 1986 WL 637507 (N.J. Super. Law Div. Nov. 18, 1986). As recognized by federal courts, Lone Pine Orders are designed to assist in the management and resolution of complex issues and potential burdens on the Court and defendants in mass tort litigation, essentially requiring plaintiffs to produce "some evidence to support a credible claim." See Steering Comm. v. Exxon Mobil Corp., 461 F.3d 598, 604 n.2 (5th Cir. 2006)(citing Acuna v. Brown & Root Inc., 200 F.3d at 340). It has been recognized that the "basic purpose of a Lone Pine Order is to identify and cull potentially meritless claims and streamline litigation in complex cases involving numerous claimants[.]" Baker v. Chevron USA, Inc., No. 05-227, 2007 WL 315346, at *1 (S.D. Ohio Jan 30, 2007).

Lone Pine Orders are particularly appropriate in pharmaceutical MDLs like MDL-1789 because Plaintiffs in these coordinated proceedings are afforded an opportunity to "park" cases with minimal risk that they will be subjected to individual attention. This may prompt counsel to accept and file cases that might be of questionable merit or value, particularly as the number of cases on the docket grows, allowing for inflated inventories with little risk that the infirmities associated with weak (or even meritless) cases will be brought to light. In the absence of a Lone Pine Order, the lack of merit will only be

exposed if the case is one of the few selected for discovery and trial. These inflated inventories impede the resolution process, as Plaintiffs are seeking settlements for claims that should never have been brought and should not be considered in the resolution equation. The obvious need to ensure that meritless cases are not swelling inventories and impeding global resolution is itself ample justification to enter a Lone Pine Order.

Indeed, use of Lone Pine Orders by courts in coordinated proceedings like this has increased such that they are now "widely used in mass torts to isolate spurious claims." David F. Herr, ANN. MANUAL FOR COMPLEX LIT. § 11.34 (4th ed. 2012). Although large pharmaceutical litigations resembling MDL-1789 comprise a small percentage of the total number of MDLs created by transfer order from the J.P.M.L., Merck has identified a full six examples of Lone Pine Orders issued in such MDLs in the last eight years alone.[3] See, e.g., In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., MDL No. 1871, 2010 WL 4720335 (E.D. Pa. Nov. 15, 2010)(Pretrial Order No. 121)(issuing a Lone Pine Order three years after the MDL was created, which stated that a licensed physician had to certify that the Plaintiff had an injury caused by Avandia); In re Zyprexa Prods. Liab. Litig., MDL No. 1596 (E.D.N.Y. June 2, 2010)(ordering plaintiffs in 61 newly filed cases to serve Rule 26(a)(2) expert reports or suffer dismissal with prejudice); In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig., MDL No. 1699 (N.D. Cal. Aug. 1, 2008)(Pretrial Order No. 29)(issuing a Lone Pine Order requiring plaintiffs to serve 26(a)(2) expert reports or risk dismissal with prejudice where litigation had been ongoing for three years, Defendants had produced large numbers of documents (see Reply Decl. of L. Brown In Support of Pfizer's Motion for Entry of *Lone Pine* Case Mgmt. Order ¶ 7,

3 For the Court's reference, Merck is attaching as Exhibit 2 to its motion copies of the Lone Pine Orders entered in these other pharmaceutical MDLs.

July 28, 2008), and common fact discovery was closed (see Pretrial Order No. 4 ¶ 1, Feb. 7, 2006); In re Vioxx Prods. Liab. Litig., MDL No. 1657 (E.D. La. Nov. 9, 2007; July 6, 2009)(Pretrial Order Nos. 28, 29, 43)(issuing a Lone Pine Order due to the advanced stage of litigation)(see In re Vioxx Prods. Liab. Litig., MDL No. 1657, 557 F.Supp.2d 741, 744 (E.D. La. May 30, 2008)); In re Rezulin Prods. Liab. Litig., MDL No. 1348, 2005 WL 1105067 (S.D.N.Y. May 9, 2005)(Pretrial Order No. 370)(issuing a Lone Pine Order affecting thousands of plaintiffs four years into the litigation)(see Def.'s Mem. of Law in Support of Mot. For Order Requiring Pls. To Produce Case-Specific Expert Reports at 1, Apr. 7, 2005); In re Baycol Prods. Liab. Litig., MDL No. 1431, 2004 WL 626866 (D. Minn. Mar. 18, 2004)(Pretrial Order No. 114)(ordering, three years after the MDL was created, that an expert had to attest that Baycol caused the Plaintiff's injuries). This recent experience demonstrates that Lone Pine is a flexible and effective procedural tool when used by MDL Courts: 1) prior to the announcement of any meaningful resolution program (*e.g.*, Avandia, Baycol, and Celebrex); 2) when some settlements had been achieved but a substantial number of non-settling cases remained on the Court's docket (*e.g.*, Rezulin and Zyprexa); as well as 3) in connection with the announcement of a settlement program that Plaintiffs would have the option to enter (Vioxx).

III. THE INDIVIDUAL CIRCUMSTANCES OF THIS MDL FAVOR ENTRY OF A LONE PINE ORDER.

Generally speaking, Lone Pine Orders are a fair and effective tool in weeding out spurious claims because they simply require plaintiffs to memorialize information they should already have. As Judge Rufe recently recognized in entering a Lone Pine Order in the Avandia MDL proceedings pursuant to which each of the more than 2,000 plaintiffs in that MDL were required to submit qualifying reports, a Lone Pine Order "merely requires information which plaintiffs and their counsel should have possessed before

filing their claims," and which they otherwise will have to produce once remanded. In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., MDL No. 1871, 2010 WL 4720335, at *1 (E.D. Pa. Nov. 15, 2010). See also Acuna v. Brown & Root Inc., 200 F.3d 335, 340 (5th Cir. 2000) (citation omitted) (holding that the district court's Lone Pine order "essentially required that information which plaintiffs should have had before filing their claims pursuant to Fed.R.Civ.P. 11(b)(3)"); Lore v. Lone Pine Corp., 1986 WL 637507, at * 4 (N.J. Super. Law. Div. Nov. 18, 1986) ("[P]rior to the institution of such a cause of action, attorneys for plaintiffs must be prepared to substantiate, to a reasonable degree, the allegations of personal injury . . . and proximate cause.").

Entry of a Lone Pine Order at this stage of MDL-1789 will in all likelihood result in the elimination of a substantial number of meritless claims, as evidenced by a review of the history of how cases have been filed, and on occasion dismissed, throughout these MDL proceedings and the state court consolidated proceedings. As listed in the chart included at p. 4, *supra*, the cases in this MDL may generally be divided into three categories:

- *First* is the docket as a whole -- *i.e.*, all cases past and present that have ever been a part of MDL-1789. This count includes over 95% of cases that have not been subjected to individual discovery or named for trial, and have thus received the least attention from the parties or the Court. This critical mass includes cases where Plaintiffs paid their court fee and filed their complaints, often using the identical form with very few changes to account for individual case factors. Once in the MDL, Plaintiffs in these cases have had little to do beyond serving their PPF responses, which give Merck basic information about the cases.

- *Second* are the cases that were selected for case-specific discovery. This category includes cases that were included on CMO-11 (the early discovery protocol), as well as cases where discovery was to begin, or did begin, based on the case being made part of the bellwether process.

- *Third* are the cases that have been set for trial, where the greatest attention is paid to them.

As shown below, the likelihood that a case is dismissed either because it is meritless, or for other reasons unknown to Merck, increases in direct proportion to the attention paid to it.

1. The MDL Docket As A Whole -- 1094 Total Cases Active Now Or In The Past, 138 Dismissed (**13%** dismissal rate).

The efficiencies gained in mass tort proceedings like this are that some cases will be subjected to more attention than others so that the overall burden on the Courts and parties alike will be less than if each case were to proceed separately. Accordingly, the majority of the cases in this MDL have not been the subject of individualized discovery and motion practice. These Plaintiffs and their attorneys have had little to do except provide their PPFs, which contain sworn responses to basic questions presented about their case.

As of the filing of this memorandum, there are 1,094 cases that have been active at one time or another in this MDL. Most of these cases (over 95%) have never been subjected to individualized discovery. In total, 138 cases that were at one time in this MDL have been dismissed. (These dismissals are usually by stipulations of dismissal submitted to this Court for signature, often following correspondence between the parties regarding deficiencies in the responses Plaintiffs have provided in their Profile Forms, or the failure of Plaintiffs to file any responsive Profile Form at all.) Thus, the dismissal rate for all cases -- including the substantial number of cases where Plaintiffs have had to do the least -- is **13%**.

2. Cases That Have Been Set For Case Specific Discovery -- 35 Total, 11 Dismissed (**31%** dismissal rate).

On June 18, 2007, this Court issued CMO-11, which identified twenty-five (25) cases that would be worked up for trial, ultimately leading to the selection of three trial

cases -- one to be selected by the PSC, one to be selected by Merck, and one to be selected by this Court. During the discovery period, Merck focused significant resources on "working up" the 25 trial pool cases. Plaintiffs dismissed four of the cases selected by Merck to be included in the trial pool -- Allen, Davis, de la Fuente, and Wade -- ensuring they could not be brought to trial.[4] Later, other cases from this initial pool dropped as Plaintiffs either voluntarily dismissed their case (Greene) or had it dismissed for lack of specific causation evidence (see Flemings Summ. J. Op. & Order at 22, Nov. 23, 2009). And, as additional bellwether cases were named later and case specific discovery was allowed to proceed in them, these cases were dismissed at a high rate, as well.

Thus, where the Court has allowed individual discovery to proceed in a case either because it was part of the early work-up protocol or because it was set for actual trial, the dismissal rates have been substantially higher (**31%**) than is the dismissal rate for the MDL as a whole (**13%**), where the substantial majority of cases have involved no additional requirement of Plaintiffs beyond their PPF obligations.[5]

3. Cases Subject To The Greatest Attention By The Court And Parties -- 12 Total, 7 Dismissed (**58%** dismissal rate).

The greatest rates of dismissal, however, have been seen in those cases where the Plaintiff's specific causation cases are most likely to be subject to scrutiny and challenge.

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4. For the Court's convenience, Merck refers in this motion to MDL-1789 cases simply by the Plaintiff's name. A chart containing the complete caption for each of the cases referenced herein is attached as Exhibit 3 to Merck's motion.

5. Merck makes its comparisons here between cases that have been subject to discovery and all cases in the MDL. The latter group of all cases includes the cases described by the former. Mathematically, Merck's comparison could be stated as looking at A (cases that have been subject to discovery) versus looking at A plus B (all cases in the MDL). If the Court is interested in comparing A versus B here separately, removing the cases that were subject to discovery from the overall docket side of the equation does not significantly affect the numbers. The dismissal rate for MDL-1789 cases not subject to individual discovery is just one percent less (12%) than is the overall dismissal rate (13%). The reason this is so is because the overall docket figures are driven significantly by the over 95% of cases that have been subject to the least attention in this MDL.

These are the cases that are set for actual trial, which are a subset of the cases referenced in section 2 above.

The first time the Court set cases for actual trial in this MDL was on October 24, 2008, when the Court issued CMO-15 that set Boles (selected by Plaintiffs), Flemings (selected by this Court), and Greene (selected by Merck) for trial. See Case Management Order 15, Oct. 24, 2008. Just five days later, Plaintiff in Greene moved to dismiss her case, and the Court granted her request.[6] See Greene Amended Op. & Order, Dec. 10, 2008. Subsequent to that, after Plaintiff in Flemings presented no qualifying specific causation opinion from either her treating physicians or a retained expert -- meaning failed to comply with what would be required by a Lone Pine Order -- that case was dismissed by November 23, 2009 order of this Court.[7] Flemings Summ. J. Op. & Order at 22, Nov. 23, 2009. Greene was subsequently replaced by Maley, (see In re Fosamax Prods. Liab. Litig., MDL No. 1789, Order, Dec. 22, 2008 (setting Maley as replacement for Greene), which was tried to defense verdict when, after twenty minutes of deliberation, the jury determined that Plaintiff did not have ONJ. See Maley Order, May 6, 2010. Graves replaced Flemings and was tried to defense verdict in November 2010. See Graves Order, Nov. 22, 2010.

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6. In its December 2008 order allowing Plaintiff in Greene to dismiss her case, the Court scolded Merck for urging that a case be kept part of the bellwether process despite its obvious specific causation infirmities and Plaintiff's willingness to voluntarily dismiss: "The only reason to hold these test trials is to enable the parties to asses the nature and strength of a sample of representative cases, in the hope that the exercise will inform and promote settlement negotiations…Nothing productive could come of forcing her to go to trial, and this case hardly would promote settlement." (Greene Amended Op. & Order 8, Dec. 10, 2008) (citing Manual for Complex Litig. § 22.315, at 451 (4th ed. 2005)). Now, after the bellwether process has revealed that cases like Greene likely comprise a substantial percentage of the Court's current docket, there is every reason for the Court to look again to the Manual for Complex Litigation and enter a Lone Pine Order that will productively promote settlement by addressing in a systematic manner "spurious claims," like Greene.

7. That order was subsequently upheld by a November 5, 2010 decision from the Second Circuit Court of Appeals. Flemings v. Merck, 399 Fed. Appx. 672, 673 (2d Cir. 2010).

Thus, of the initial five cases selected for trial in the initial three bellwether phase, two were dismissed before they could be tried (one voluntarily and one by Court order).

On September 9, 2010, this Court directed that two additional cases would be tried after completion of the third MDL trial (Graves). See In re Fosamax Prods. Liab. Litig., MDL No. 1789, Order, Sept. 9, 2010. Plaintiffs selected Secrest, (see In re Fosamax Prods. Liab. Litig., Order, Sept. 23, 2010), which was tried to defense verdict in October 2011. See Secrest Order, Oct. 4, 2011. Merck originally chose Hester as its trial selection, (see In re Fosamax Prods. Liab. Litig., MDL No. 1789, Order, Sept. 23, 2010), which was dismissed near the end of fact discovery, with Plaintiff agreeing to pay certain costs in the case. See Hester Stipulation & Order of Dismissal with Prejudice, Apr. 15, 2011. Merck then chose Raber to replace Hester; Raber was dismissed after Plaintiff refused to appear for trial. See In re Fosamax Prods. Liab. Litig., MDL No. 1789 (S.D.N.Y. Oct. 20, 2012)(dismissing Raber).

Thus, of the next three cases selected for trial in the second bellwether phase, two were dismissed before they could be tried (again one voluntarily and one by order of the Court).

The third bellwether phase in this MDL was to involve two post-ONJ label change cases. By order dated October 20, 2011, the Court set two post-label change cases for trial: Jellema was set for trial beginning May 7, 2012 and Spano was set for trial beginning September 10, 2012. See In re Fosamax Prods. Liab. Litig., MDL No. 1789, Order, Oct. 20, 2011. Predictably, both Plaintiffs dismissed their cases -- the Jellema Plaintiff on November 2, 2011 (see Jellema Stip. & Order of Dismissal with Prejudice, Nov. 12, 2011) and the Spano Plaintiff on March 5, 2012 (see Spano Stip. & Order of Dismissal with Prejudice, Mar. 5, 2012). Finally, on March 29, 2012, the Court

selected two cases to be worked up for trial in January 2013 so the parties could try at least one post-label change case -- one lead case (Scheinberg), and one back-up case (Diamond), in case the lead case was dismissed. See In re Fosamax Prods. Liab. Litig., MDL No. 1789, Order, Mar. 29, 2012. On July 30, 2012, Plaintiff in Diamond dismissed her case, too. See Diamond Stip. & Order of Dismissal with Prejudice, July 30, 2012.

Thus, of the four cases in the third bellwether phase in which trial dates have been set, three have already been dismissed. And, in total, taking all three bellwether phases, a full seven of the twelve cases set for trial were dismissed -- five by Plaintiffs and two by the Court -- before they could possibly be tried.

4. The Experience In The New Jersey State Coordinated ONJ Proceedings Confirms The Above Experience Seen In The MDL-1789 Docket.

While this Court is likely concerned primarily with the cases currently on its docket that may ultimately be eligible for remand if no resolution is achieved, there is a separate data set of like cases that strongly reinforces what has been seen in the MDL. Namely, there have been a total of 276 cases filed in the New Jersey state coordinated proceedings involving allegations that Fosamax caused a plaintiff's ONJ. The history of cases set for discovery and trial in the New Jersey coordinated proceedings is telling.

- On October 14, 2009, Judge Higbee ordered that ten cases be worked up for full discovery -- five selected by Plaintiffs and five selected by Merck. In Re: FOSAMAX Litigation, No. 282, Case Management Order (N.J. Super. Law Div. Oct. 14, 2009.) Plaintiffs dismissed all five of Merck's selections and two of Plaintiffs' selections, meaning seven of the ten cases selected by the parties were simply dismissed.

- By Order dated March 4, 2010, Merck was permitted to name three replacement cases. In Re: FOSAMAX Litigation, No. 282, Core Discovery Order Relating to Second Tier Discovery Pool Cases (N.J. Super. Law Div. Mar. 4, 2010.) Plaintiffs dismissed all three replacement selections.

- Then, by Order dated September 14, 2010, Merck was permitted to name five replacement cases and Plaintiffs were permitted to identify five

> additional cases for full discovery. In Re: FOSAMAX Litigation, No. 282, Core Discovery Order Relating to Third Tier Discovery Pool Cases (N.J. Super. Law Div. Sept. 14, 2010.) Plaintiffs dismissed two more of Merck's selections before full discovery was even completed.

Thus, in New Jersey, more than half (12/23) of the cases set for discovery and possible trial have been dismissed.

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This demonstrates that where Plaintiffs' specific causation cases have been put in focus, either in this MDL or elsewhere, a substantial percentage of the cases are shown to be non-meritorious and are dismissed. Dismissals increase at a rate commensurate with the attention paid to them. And, while Plaintiffs and their counsel with suits currently pending in MDL-1789 should have been able to provide ample basis for their specific causation claims from the day their suits were filed, the vast majority of Plaintiffs have had substantial time to confirm their specific causation cases. In MDL-1789, there has been six years of extensive scientific and factual discovery from Merck, and five bellwether trials of four separate cases. The majority of these Plaintiffs have had the benefit of time in these proceedings as over 90% of the cases currently in this MDL have been on this Court's docket for over eighteen months.[8] Throughout this time, Plaintiffs have consistently dismissed their claims at a high rate when pressed to justify or pursue them.

Thus, all the factors that militate in favor of Lone Pine Orders -- *e.g.*, mature discovery and a developed record in the MDL, the demonstrated presence of spurious claims on the docket, and a record of Plaintiffs' dismissing non-meritorious cases when pressed to provide a justification for them -- are present here. There is thus every reason

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8. Looking at the filings differently, only 26 of the over 1,000 ONJ cases that have been a part of this MDL were filed in 2012.

to believe that a Lone Pine Order will accomplish what the bellwether process has begun -- isolating and dismissing from the Court's docket non-meritorious claims -- except on a broader scale.[9]

IV. THE PROPOSED LONE PINE ORDER IS APPROPRIATE IN SCOPE AND WOULD PUT INTO PLACE A NECESSARY, TIMELY AND EFFICIENT PROCESS FOR IDENTIFYING AND ELIMINATING SPURIOUS CLAIMS.

Merck anticipates that PSC, speaking for Plaintiffs, will once again oppose any Lone Pine procedures based on alleged duty, burden, and delay. None provide a valid basis for foregoing Lone Pine procedures in MDL-1789, especially when each is weighed against the unquestioned benefits such a process would likely yield.

Requiring each Plaintiff in this MDL to now come forward with a verified report from an appropriately qualified expert asserting that Fosamax caused the alleged injury will not impose any novel duty upon that plaintiff. Proof of both "injury" and "causation" are essential elements that plaintiffs bear the burden of proving in their cases-in-chief, the basis for which is information that should have been known to Plaintiffs when they filed their complaints, and certainly should be known by now. See, e.g., In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., MDL 1871, 2010 WL 4720335, at *1 (E.D. Pa. Nov. 15, 2010)(A Lone Pine Order "merely requires information which plaintiffs and their counsel should have possessed before filing their claims.").

Nor will Lone Pine procedures impose an undue burden on any individual Plaintiff or Plaintiff's attorney. The schedule Merck has proposed staggers by last name

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9. Although this MDL has focused on the cases brought by a core group of PSC attorneys, interactions with other Plaintiffs' attorneys suggest that there may be non-meritorious cases among the cases brought by these other attorneys. For example, when the Court offered Plaintiff in the Boland case the opportunity to execute a Lexecon waiver and travel from Long Island to S.D.N.Y. for a trial last year, her attorney stated on the record "Well, I mean this particular client would prefer to get her case settled than to have to go through a trial. Most of the cases in the MDL end up settling." (Tr. 4:23-25, Nov. 7, 2011.)

the timing for providing the reports and is tailored to this MDL where there has been extensive scientific discovery, five bellwether trials and more than a 50% dismissal rate when attention is paid to a particular case. Under these circumstances, it is entirely appropriate for this Court to exercise its discretion and order each Plaintiff in this MDL to provide this minimal substantiation of their claims. See, e.g., In re Vioxx Prods. Liab. Litig., 557 F. Supp. 2d 741, 744 (E.D. La. May 30, 2008)("At this advanced stage of the litigation, it is not too much to ask a Plaintiff to provide some kind of evidence to support their claim that Vioxx caused them personal injury.").

Moreover, the Lone Pine procedures Merck has proposed will not delay the resolution of any claims. Merck has attempted to balance the ability of Plaintiffs and their attorneys to complete their compilation of the information by staggering the time for completion of these reports over roughly six months. And, if Plaintiffs so desire, Merck would be amenable to discussing a compressed time frame. The entire Lone Pine process Merck proposes -- *that would provide information on nearly one thousand cases*-- is roughly identical to that required to prepare for trial in an individual bellwether case. Plaintiffs, and in particular PSC counsel, who just a year ago dismissed a case at the close of discovery *seven months* after it was selected for trial -- Hester -- leaving no case to be tried in its stead last spring or summer, should not be heard to now complain about delay. See In re Fosamax Prods. Liab. Litig., MDL No. 1789, Order, Sept. 23, 2010 (scheduling Hester for trial beginning on May 9, 2011); Hester v. Merck and Co., Inc., No. 06-9450, Stipulation & Order of Dismissal, Apr. 15, 2011 (Plaintiff in Hester voluntarily dismissed her case less than one month before trial scheduled to begin). The primary stage of the Lone Pine process Merck proposes will be nearing completion when a verdict in Scheinberg is reached.

Here, the cost/benefit equation overwhelmingly favors entry of the CMO Merck seeks. An appropriate Lone Pine Order will, among other things, require each Plaintiff to proffer an affidavit from a qualified expert opining that the Plaintiff suffers from an injury that was caused by Fosamax, will have both the effect of identifying cases that can even arguably be maintained, and will also tell the parties something about these cases. The process will facilitate discussions regarding resolution as the parties will no longer be left to guess at the likely number of inarguably meritless cases that populate the docket. Having these non-meritorious cases on the docket benefits no party seeking to do justice nor this or any other Court. Lone Pine is perfectly suited for these circumstances because this process can only efficiently be overseen by this Court, as it is not an option after remand.

The Lone Pine Order Merck seeks for the pending MDL cases is consistent with what other MDL Courts have done to great effect when faced with litigation where significant discovery had been exchanged and plaintiffs had demonstrated an inability to support their claims when pressed. Specific examples include:

- **AVANDIA (MDL-1871)** -- In issuing a Lone Pine Order that required each of the more than 2,000 Plaintiffs in the MDL to provide additional support for their claims, Judge Rufe found that this process was "necessary in furtherance of settlement agreements, for the selection of cases for bellwether trials, and for the timely remand of cases to the sending courts for resolution." In re Avandia Mktg. Sales Practices and Prods. Liab. Litig., MDL No. 1871, 2010 WL 4720335, at *1 (E.D. Pa. Nov. 15, 2010)(Pretrial Order No. 121). There, the court issued the Lone Pine Order (in November 2010) after some cases were already resolved through settlement but prior to the implementation of any meaningful resolution program. Approximately fourteen months later (January 2012), the parties entered a large scale settlement agreement. See Avandia Stipulation & Order at 1, July 10, 2012 (noting that the Confidential Master Settlement Agreement became effective January 12, 2012). Judge Rufe's concern about the ability of the plaintiffs to substantiate their claims was validated when plaintiffs in approximately half of the 2,000 cases subject to that Lone Pine Order were unable to submit the required

certifications. See Glaxosmithkline LLC's Reply in Further Support of Mot. for a *Lone Pine* Case Mgmt. Order at 4, In re Avandia Litig. No. 0802-2733 (Phila. Ct. of Com. Pl. Jan. 28, 2011).

- **REZULIN (MDL-1348)** -- In Rezulin, where the litigation had been ongoing for four years and, as here, ample discovery had occurred that could assist plaintiffs in culling their viable claims, Defendants argued for a Lone Pine Order for expert reports for more than 1,000 cases and 5,000 plaintiffs. See Def.'s Mem. of Law in Support of Mot for Order Requiring Pls. to Produce Case-Specific Expert Reports, In re Rezulin Prods. Liab. Litig., MDL No. 1348 (Apr. 7, 2005). Judge Kaplan agreed and ordered that each plaintiff in that MDL had to consider if they had good ground to continue the litigation and if so, submit a Rule 26(a)(2) expert report. The Court was "satisfied that this course is essential to the fair and efficient administration of this litigation." In re Rezulin Prods. Liab. Litig., MDL No. 1348, 2005 WL 1105067, at *1 (S.D.N.Y. May 9, 2005)(Pretrial Order No. 370).

- **BAYCOL (MDL-1431)** -- Judge Davis issued a Lone Pine Order ordering each plaintiff who wished to pursue their case to file a Rule 26(a)(2) expert report similar to the one sought by Merck here. In re Baycol Prods. Liab. Litig., MDL 1431, 2004 WL 626866 (D. Minn. Mar. 18, 2004)(Pretrial Order No. 114). That order was issued after two years of litigation in the MDL, several trials had resulted in defense verdicts, there was a demonstrated history of plaintiff dismissals when pressed to pursue their cases. Bayer and GSK's Opp. To PSC's (a) Mot. to Stay Enforcement of PTOs 114, 127 & 131; (b) Mot. to Impose a Case-Specific Expert Reporting Req. Upon Defs; and (c) Latest Comprehensive Case Mgmt. Proposal at 4, Feb. 2, 2005. When that Order was stayed a year later by Pretrial Order 138, 3,700 plaintiffs had been dismissed (or were in the process of dismissal) either by stipulation or court order. Id. at 5.

CONCLUSION

For the above reasons, the Court should grant Merck's motion for entry of a Lone Pine Order and should require each Plaintiff to submit a case-specific expert report to enable the Court to better evaluate the merits of the remaining Plaintiffs' claims.

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